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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,031	11/24/2003	Robert G. Parsons	7098.US.P1	4754
23492	7590	10/24/2006	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1657	
DATE MAILED: 10/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/721,031

Applicant(s)

PARSONS ET AL.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-106 is/are pending in the application.
- 4a) Of the above claim(s) 1-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 95-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicant's election with traverse of Group V, claims 95-106 in the reply filed on 8/14/06 is acknowledged. The traversal is on the ground(s) that it would not be a burden to search all Groups. This is not found persuasive because each of the groups are distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

Please inform the examiner as to how the present CIP application differs from the parent application to properly determine the priority date.

The abstract of the disclosure is objected to because it is not directed to the presently claimed invention. Correction is required. See MPEP § 608.01(b).

Please inform the examiner of all related applications, patented, pending or abandoned.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 95-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bergmann in view of each of Chen and Flaa.

Bergmann (5,541,116) entitled "Method for the Stabilization of Endogenous, Physiologically Active Peptides" teaches in column 2 line 21, EDTA, and on lines 38-39, ANP. In column 3 lines 20-24, EDTA is a protease inhibitor and a buffer is added. In column 4 line 26 a phosphate buffer is employed. In column 5 line 2 aprotinin is shown.

The claims differ from Bergmann in that they specify a pH range and some of the dependent claims include additional stabilizing substances.

Chen (6,525,102 B1) entitled "Stabilized Liquid Polypeptide Containing Pharmaceutical Compositions" teaches in column 1 line 28, pH affects stability of polypeptides. In column 2 lines 24-29, buffers are described. In column 2 line 40 EDTA is shown to increase stability of polypeptides. In column 10 first paragraph, pH ranges of 5-6.5 are taught regarding the pH optimum for stability of a particular polypeptide of interest. In column 24 lines 25-37, how the optimum pH was determined is shown.

Flaa (WO 96/27661) entitled "Stabilizing Solutions for Proteins and Peptides" teaches on page 7 last paragraph, a composition for stabilizing proteins containing buffer, albumin, chelating agent, reducing agent at a mildly alkaline pH. On page 8 the stabilizing protein may be albumin or casein. On page 9 protease inhibitors and preservatives may be used. On page 9 line 9 phosphate buffers are shown. On page 10 line 5 BSA is taught. On page 10 line 25 EDTA is seen. On page 11 line 10, the pH range is 5-7.5. On page 11 line 15 aprotinin is shown along with other known protease inhibitors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to stabilize natriuretic peptides as taught by Bergmann at the pH ranges and with the additional substances taught by each of Chen and Flaa because both Chen and Flaa teach stabilizing various polypeptides for the same function as claimed at the pH range and with the substances as presently claimed. To stabilize any polypeptide with a pH range and substances known to stabilize polypeptides with the expected results would have been obvious. No novelty is seen in the claimed compounds such as sodium hydroxide in obtaining a desired pH range or to make a buffer solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ralph Gitomer  
Primary Examiner  
Art Unit 1655

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GROUP 1200